DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ***"The AHRQ Safety Program for Methicillin-Resistant Staphylococcus aureus (MRSA) Prevention."*** This proposed information collection was previously published in the Federal Register on May 3rd, 2021 and allowed 60 days for public comment. AHRQ did not receive any substantive comments from members of the public. The purpose of this notice is to allow an additional 30 days for public comment.

DATES: Comments on this notice must be received by **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].**

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain . Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427-1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

The AHRQ Safety Program for Methicillin-Resistant Staphylococcus aureus (MRSA) Prevention

As part of the HHS HAI National Action Plan (NAP), AHRQ has supported the implementation and adoption of the Comprehensive Unit-based Safety Program (CUSP) to reduce Central-Line Associated Bloodstream Infections (CLABSI) and Catheter-Associated Urinary Tract Infections (CAUTI), and subsequently applied CUSP to other clinical challenges, including reducing surgical site infections and improving care for mechanically ventilated patients. As part of the National Action Plan for Combating Antibiotic-Resistant Bacteria (CARB NAP), the HHS HAI National Action Plan, and Healthy People 2030 goals, AHRQ will now apply the principles and concepts that have been learned from these HAI reduction efforts to the prevention of MRSA invasive infections.

Healthcare-associated infections, or HAIs, are a highly significant cause of illness and death for patients in the U.S. At any given time, HAIs affect one out of every 31 hospital inpatients. More than a million of these infections occur across our health care system every year. This leads to significant patient harm and loss of life, and costs billions of dollars each year in medical and non-medical costs. In addition, the 3 million Americans currently residing in U.S. nursing homes experience a staggering 2-3 million HAIs each year.

Particular concern has arisen related to the persistent prevalence of methicillin-resistant Staphylococcus aureus (MRSA). This bacterium affects both communities and healthcare facilities, but the majority of morbidity and mortality occurs in critically and chronically ill patients. While MRSA was rare in the US through the 1970s, its prevalence in US health care

facilities began rising in the 1980s and has continued to do so. In 2000, MRSA was responsible for 133,510 hospitalizations in children and adults. This number more than doubled by 2005, with 278,203 hospitalizations along with 56,248 septic events and 6,639 deaths being attributed to MRSA. MRSA has become a major form of hospital-associated Staphylococcus aureus infection.

For various patient safety initiatives, AHRQ has promoted the implementation and adoption of the Comprehensive Unit-based Safety Program (CUSP) approach which combines clinical and cultural (i.e., technical and adaptive) intervention components to facilitate the implementation of technical bundles to improve patient safety. For MRSA prevention, it is likely that a combination of technical approaches is indicated, including decolonization along with classic infection control practices such as hand hygiene, environmental cleaning, general HAI prevention, and contact precautions/isolation. Implementation of these technical approaches would benefit greatly from the cultural and behavioral interventions incorporated in CUSP. AHRQ expects that this approach, which includes a focus on teamwork, communication, and patient engagement, will enhance the effectiveness of interventions to reduce MRSA infection that will be implemented and evaluated as part of this project.

This project will assist hospital units and long-term care facilities in adopting and implementing technical approaches to reduce MRSA infections. It will be implemented in four cohorts:

- at least 400 ICUs
- at least 400 non-ICUs
- at least 300 hospital surgical services

- at least 300 long-term care facilities.

The goals of this project are to 1) develop and implement a program to prevent MRSA invasive infection in intensive care units (ICUs), non-ICUs, inpatient surgery, and long-term care facilities, 2) assess the adoption of CUSP for MRSA Prevention, and 3) evaluate the effectiveness of the intervention in the participating units. AHRQ is requesting a 3-year clearance to perform the data collection activities needed to assess the adoption of the program and evaluate its effectiveness in the participating units and facilities.

The project is being conducted by AHRQ through its contractor, Johns Hopkins University (JHU) and JHU's subcontractor, NORC at the University of Chicago. The project is being undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions (42 U.S.C. 299).

Method of Collection

The evaluation will utilize an interrupted time series design to assess MRSA invasive infections (defined as MRSA bacteremia) and secondary clinical outcomes, using 18 months of implementation data and 12 months of retrospective data. We will also assess needs of participating units and capacity to implement the intervention, awareness of MRSA prevention, implementation fidelity and effectiveness, communication and teamwork, and changes in patient safety culture and behavior using a pre-post design.

The primary data collection includes the following:

1) Unit or Facility-level clinical outcome change data: The program will use a secure online portal to collect clinical outcomes measures extracted from site electronic health record (EHR) systems for the 12 month period prior to the start of the implementation, as well as for the 18 month implementation period. These data will be used to evaluate the effectiveness of the *AHRQ Safety Program for MRSA Prevention*.

2) Survey of Patient Safety Culture: The NORC/JHU team will administer AHRQ Surveys of Patient Safety Culture to all eligible AHRQ Safety Program for MRSA Prevention staff at the participating units or facilities at the beginning and end of the intervention. We will administer the Hospital Survey of Patient Safety Culture (HSOPS) in the ICU, non-ICU, and surgical cohorts, and the Nursing Home Survey on Patient Safety Culture (NHSOPS) in the long term care cohort. These surveys ask questions about patient safety issues, medical errors, and event reporting in the respective setting. NORC/JHU will request that all staff on the unit or facility that is implementing the AHRQ Safety Program for MRSA Prevention complete the survey. As unit and facility size vary, we estimate the average number of respondents to be 25 for each unit.

3) Infrastructure Assessment Tool- Gap Analysis: The NORC/JHU team will administer the Gap Analysis during the first month of the intervention to an Infection Preventionist and one of the unit's team leaders (most likely a nurse). Information on current practices in MRSA prevention on the unit will be collected.

4) Implementation Assessments- Team Checkup Tool: The implementation assessments will be conducted to monitor the program's progress and determine what the participating sites have learned through participating in the program. The Team Checkup Tool will be requested monthly, and we anticipate participation from approximately 1 staff (most commonly a nurse) per unit. The program will use the Team Checkup Tool to monitor key actions of staff members.

The Tool asks about use of safety guidelines, tools, and resources throughout three different phases: Assessment (1), Planning, Training, and Implementation (2), and Sustainment (3).

This data collection effort will be part of a comprehensive evaluation strategy to assess the adoption of the Comprehensive Unit-Based Safety Program (CUSP) for MRSA Prevention in ICUs, non-ICUs, surgical services, and long-term care settings; and measure the effectiveness of the interventions in the participating facilities or units. The evaluation has four main goals:

1. Program participation: Assess the ability of sites to successfully encourage full participation of unit/facility staff in educational activities.

2. Implementation and adoption: Assess the implementation and adoption of CUSP for MRSA prevention.

3. Program effectiveness: Measure the effectiveness of the CUSP for MRSA prevention bundle.

4. Causal pathways: Describe the characteristics of teams that are associated with successful implementation and improvement outcomes.

Estimated Annual Respondent Burden

Exhibit 1 shows the total estimated annualized burden hours for the data collection efforts. All data collection activities are expected to occur within the three-year clearance period. The total estimated annualized burden is 11,552 hours.

Exhibit 1 Estimated annualized burden hours

Form Name	Number of Respondents +	Number of responses per respondent	Hours per response	Total Burden hours
Survey of Patient Safety Culture				
HSOPS *(25 respondents per unit, pre- and post-implementation for ICU (400), non-ICU (400), and surgical (300) cohorts, 1,100 units total)*	**9,167**	**2**	**0.25**	**4,584**
NHSOPS *(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)*	**2,500**	**2**	**0.25**	**1,250**
Infrastructure Assessment				
Gap Analysis *(1 assessment per unit or facility, pre and post-*	**467**	**2**	**1**	**934**

implementation for all four cohorts, 1,400 sites total)				
Implementation Assessments:				
Team Checkup Tool ***(1 checklist conducted monthly during the 18 months of implementation for ICU, non-ICU, and Surgical cohorts, 1,100 units total)***	**367**	**18**	**0.17**	**1,123**
Team Checkup Tool ***(1 checklist conducted monthly per facility during the 18 month implementation period for LTC cohort, 300 facilities total)***	**100**	**18**	**0.17**	**306**
Electronic Health Record (EHR) Extracts				
Initial data pull for 10% of hospitals that do not confer rights to their NHSN data	**27**	**1**	**5**	**135**

(once at baseline for ICU and non-ICU cohorts, 800 units total)				
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (once at baseline for ICU and non-ICU cohorts, 800 units total)	**267**	**1**	**3.5**	**935**
Initial data pull for 10% of units that submit point prevalence survey data (once at baseline for ICU and non-ICU cohorts, 800 units total)	**27**	**1**	**0.5**	**14**
Initial data pull for 20% of surgical units that do not confer rights to NHSN data	**20**	**1**	**0.5**	**10**

(once at baseline for Surgical cohort, 300 settings total)				
Initial data pull **(once at baseline for LTC cohort, 300 facilities total)**	**100**	**1**	**5**	**500**
Quarterly data collection of monthly data ***(quarterly during 18 months of implementation for ICU and non-ICU, cohorts, 800 units total)***	**267**	**6**	**0.5**	**801**
Quarterly data collection of monthly data for 20% of hospitals that do not confer rights to their NHSN data (*quarterly during 18 months of implementation for*	**20**	**6**	**0.5**	**60**

***surgical cohorts, 300 units total*)**				
Monthly data ***(monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)***	**100**	**18**	**0.5**	**900**
Total	**13,429**			**11,552**

+ The number of respondents per data collection effort is calculated by multiplying the number of respondents per unit by the total number of units. The result is divided by three to capture an annualized number.

Exhibit 2 shows the estimated annualized cost burden based on the respondents' time to complete the data collection activities. The total annualized cost burden is estimated to be $540,325.83.

Exhibit 2 Estimated annualized cost burden

Form Name	**Number of Respondents**	**Total Burden Hours**	**Average Hourly Wage Rate**	**Total Cost Burden**
Survey of Patient Safety Culture				

HSOPS ***(25 respondents per unit, pre- and post-implementation for ICU (400), non-ICU (400), and surgical (300) cohorts, 1,100 units total)***	**9,167**	**4,584**	**$51.53***	**$236,187.76**
NHSOPS ***(25 respondents per facility, one response per pre- and post-implementation for LTC cohort, 300 facilities total)***	**2,500**	**1,250**	**$51.53***	**$64,412.50**
Infrastructure Assessment				
Gap Analysis ***(1 assessment per unit or facility, pre and post-implementation for all four cohorts, 1,400 sites total)***	**467**	**934**	**$51.53***	**$48,129.02**
Implementation Assessments:				

Team Checkup Tool *(1 checklist conducted monthly during 3 months of ramp-up and 15 months of implementation periods for ICU, non-ICU, and Surgical cohorts, 1,100 units total)*	**367**	**1,123**	**$51.53***	**$57,868.19**
Team Checkup Tool *(1 checklist conducted monthly per facility during 18 months of implementation for LTC cohort, 300 facilities total)*	**100**	**306**	**$51.53***	**$15,768.18**
Electronic Health Record (EHR) Extracts				
Initial data pull for 10% of hospitals that do not confer rights to their NHSN data	**27**	**135**	**$35.17^**	**$4,747.95**

(once at baseline for ICU and non-ICU cohorts, 800 units total)				
Initial data pull for hospital onset bacteremia (including MSSA) and MRSA-positive clinical cultures (not available in NHSN) (once at baseline for ICU and non-ICU cohorts, 800 units total)	**267**	**935**	**$35.17^**	**$32,866.37**
Initial data pull for 10% of units that submit point prevalence survey data (once at baseline for ICU and non-ICU cohorts, 800 units total)	**27**	**14**	**$35.17^**	**$474.80**

Initial data pull for 20% of surgical settings that do not confer rights to NHSN data **(once at baseline for Surgical cohort, 300 settings total)**	**20**	**10**	**$35.17^**	**$351.70**
Initial data pull **(once at baseline for LTC cohort, 300 facilities total)**	**100**	**500**	**$35.17^**	**$17,585.00**
Quarterly data ***(quarterly during 18 months of implementation for ICU and non-ICU cohorts, 1,100 units total)***	**267**	**801**	**$35.17^**	**$28,171.17**
Quarterly data collection of monthly data for 20% of hospitals that do not	**20**	**60**	**$35.17^**	**$2,110.20**

confer rights to their NHSN data (*quarterly during 18 months of implementation for surgical cohorts, 300 units total*)				
Monthly data *(monthly per facility during 18 months of implementation for LTC cohort, 100 facilities total)*	**100**	**900**	**$35.17^**	**$31,653.00**
Total	**13,429**	**11,552**		**$540,325.83**

***This is an average of the average hourly wage rate for physician, nurse, nurse practitioner, physician's assistant, and nurse's aide from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).**

^This is an average of the average hourly wage rate for nurse and IT specialist from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

^This is an average of the average hourly wage rate for nurse and IT specialist from the May 2019 National Occupational Employment and Wage Estimates, United States, U.S. Bureau of Labor Statistics (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

Request for Comments

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501-3520, comments on AHRQ's information collection are requested with regard to any of the following: (a) whether the proposed collection of information is necessary for the proper performance of AHRQ's health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Dated: July 19, 2021.

Marquita Cullom,

Associate Director.

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